

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 75-326

CHEMISTRY REVIEW(S)

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Chemistry, #38, 2/12/99

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Chemistry, #38, 6/30/98

1. CHEMISTRY REVIEW NO 4
2. ANDA 75-326
3. NAME AND ADDRESS OF APPLICANT

Eon Labs Manufacturing, Inc.
Attention: Sadie M. Ciganek
227-15 N. Conduit Avenue
Laurelton, NY 11413

4. LEGAL BASIS FOR SUBMISSION

The reference listed drug's marketing exclusivity expired on 10/31/96. U.S. Patent # 4591592 will expire on 5/27/03. The firm has included a statement that their product will not infringe upon the above patent. As per 21 CFR 314.95(a) and (b), the firm has sent a notice of Certification to Syntex Inc.

5. SUPPLEMENT(s)

N/A

6. PROPRIETARY NAME

None

7. NONPROPRIETARY NAME

Ticlopidine Hydrochloride Tablets

8. SUPPLEMENT(s) PROVIDE(s) FOR:

N/A

9. AMENDMENTS AND OTHER DATES:

Firm

Original filing - 1/30/98
New Correspondence - 3/20/98
Amendment - 4/30/98
Major amendment - 7/30/98
New correspondence - 3/4/99
Amendment - 3/17/99
Label amendment - 4/27/99
New correspondence - 6/22/99
Amendment - 6/28/99

FDA

ANDA acceptable for filing - 2/26/98
CMC, label deficiency fax - 6/30/98
Label letter re: educational program - 9/21/98
Bio specification for dissolution - 10/28/98
Chemistry deficiencies - 2/12/99
Phone call by K. Sherrod/chemist/TL with Firm/3/1/99
Labeling deficiencies - 3/11/99
Method validation results - 3/12/99
Chemistry deficiency - 6/11/99
Label approval letter - 6/10/99
Label letter re: post-approval educational plan - 6/15/99

10. PHARMACOLOGICAL CATEGORY 11. Rx or OTC
To reduce the risk of thrombotic Rx
stroke
12. RELATED IND/NDA/DMF(s)
13. DOSAGE FORM
Off-white, oval shaped film coated tablets with imprints
E115 on one side and plain on the other side.
14. POTENCY
250 mg
15. CHEMICAL NAME AND STRUCTURE
5-[(2-Chlorophenyl)methyl]-4,5,6,7-tetrahydrothieno [3,2-c]
pyridine hydrochloride
M.W. = 300.25
16. RECORDS AND REPORTS
None
17. COMMENTS
None
18. CONCLUSIONS AND RECOMMENDATIONS
No outstanding Chemistry issues; approval recommended.
19. REVIEWER: DATE COMPLETED:
Radhika Rajagopalan, Ph.D. 7/21/99

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8/6/99

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Chemistry #20 - #37, 8/6/99